

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TAKEDA PHARMACEUTICALS U.S.A., INC.,)
)
Plaintiff,)
)
v.) Civ. No. 14-1268-SLR
)
WEST-WARD PHARMACEUTICAL)
CORPORATION, HIKMA AMERICAS, INC.,)
and HIKMA PHARMACEUTICALS PLC,)
)
Defendants.

MEMORANDUM ORDER

At Wilmington this 14th day of December, 2016, having reviewed plaintiff's motion filed pursuant to Rules 59(e) and 15(a) of the Federal Rules of Civil Procedure, as well as the papers filed in connection therewith;

IT IS ORDERED that said motion (D.I. 124) is granted, for the reasons that follow:

1. **Standard of review.** After the entry of final judgment, Federal Rule of Civil Procedure 59(e) provides a plaintiff with a "window in which to seek to reopen the judgment and amend the complaint." *Fletcher-Harlee Corp. v. Pote Concrete Contractors, Inc.*, 482 F.3d 247, 253 (3d Cir. 2007). Under Rule 59(e), "[a] motion to alter or amend a judgment must be filed no later than 28 days after the entry of judgment." When a plaintiff files a Rule 59(e) motion accompanied by a Rule 15(a) motion after the dismissal of a complaint under Rule 12(b)(6), "the appropriate manner

to dispose of this issue is to consider the motions together and determine what outcome is permitted by consideration of the Rule 15(a) factors.” *Burtch v. Milberg Factors, Inc.*, 662 F.3d 212, 231 (3d Cir. 2011). “Under Rule 15(a), if a plaintiff requests leave to amend a complaint vulnerable to dismissal before a responsive pleading is filed, such leave must be granted in the absence of undue delay, bad faith, dilatory motive, unfair prejudice, or futility of amendment.” *Grayson v. Mayview State Hosp.*, 293 F.3d 103, 108 (3d Cir. 2002). See also *Foman v. Davis*, 371 U.S. 178, 182 (1962).

2. Background. On October 3, 2014, plaintiff Takeda Pharmaceuticals U.S.A., Inc. (“Takeda”) filed the instant suit, asserting induced infringement of five patents under 35 U.S.C. § 271(b). On October 9, 2014, the court issued a temporary restraining order (“TRO”), but denied Takeda’s request for a preliminary injunction (“PI”) on November 4, 2014. On appeal, the Federal Circuit affirmed the court’s denial of a PI and vacated the TRO. *Takeda Parms. U.S.A., Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 625, 627 (Fed. Cir. 2015). On September 10, 2015, Takeda filed its first amended complaint, which defendants Hikma Americas Inc. and Hikma Pharmaceuticals PLC (collectively, “Hikma”) moved to dismiss. On May 18, 2016, the court granted Hikma’s motion, and the case was closed.

3. In its first amended complaint, Takeda alleged that Hikma’s Mitigare™ product¹ induced infringement of certain of Takeda’s patents, which contain one or more claims covering methods of use of Takeda’s colchicine product, Colcrys®. (D.I.

¹An oral single-ingredient colchicine product, “indicated for prophylaxis of gout flares in adults.” (D.I. 1, ex. H at 1)

109) Colcrys® is approved and used to treat and prevent acute gout flares. Although Mitigare™ has the same active ingredient, route of administration, and strength as Colcrys®, Mitigare™ is approved only to prevent gout flares, and the Mitigare™ label warns that it is not indicated for the treatment of acute gout flares. The court reviewed the labels of the accused Mitigare™ products, as well as Hikma's FDA correspondence and evidence of Hikma's marketing and sales activities. The court concluded that, on its face, the Mitigare™ labels did not infringe. With respect to Hikma's marketing and sales activities, the court concluded that Takeda had failed to satisfy the pleading standard found in *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007), and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009);² i.e., Takeda had failed to provide adequate factual allegations to set forth a plausible claim for induced infringement.

4. Analysis. Takeda comes to the court with a second amended complaint, arguing that it "has amended its allegations to clearly state a claim based on Hikma's active encouragement of third-party infringement, including Mitigare sales representatives' statements telling healthcare providers to prescribe Mitigare for the unapproved indications covered by Takeda's patents, including for the treatment of acute gout flares, and its distribution of a sales aid which explicitly references the ACR Guidelines that recommend Takeda's patented methods." (D.I. 125 at 2; see also D.I. 125, ex. A, ¶¶ 49-66) Hikma observes in its opposition brief that "Takeda offers no details concerning any of these conversations - no particulars concerning which

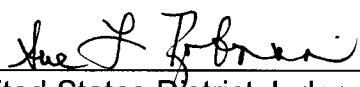
²Takeda notes that it was unfair for the court to judge the first amended complaint against this heightened standard of review, as opposed to that related to Form 18.

providers told **which** Takeda representatives of statements by **which** Hikma representatives, or **when** these conversations supposedly occurred.” (D.I. 127 at 2) (emphasis in original)

5. With respect to the factors related to the Rule 15(a) motion, the motion was timely, and there is no evidence of bad faith or dilatory motive under the circumstances at bar, that is, patent litigation between aggressive competitors trying to achieve market share. The court is mindful, however, that the purpose of a complaint is “to give the defendant fair notice of what the . . . claim is and the grounds upon which it rests.” *Twombly*, 550 U.S. at 545 (internal quotation marks omitted). So long as a plaintiff has not used “boilerplate and conclusory allegations,” and has accompanied its legal theory with “factual allegations that make [its] theoretically viable claim plausible,” the Third Circuit has held “pleading upon information and belief [to be] permissible where it can be shown that the requisite factual information is peculiarly within the defendant’s knowledge or control.” *McDermott v. Clondalkin Grp., Inc.* 2016 WL 2893844, at *4 (3d Cir. May 18, 2016) (quotation marks, citation, and emphasis omitted). A filed pleading that rests upon information and belief must be “formed after an inquiry reasonable under the circumstances,” such that “the factual contents have evidentiary support, or if so identified, will likely have evidentiary support after a reasonable opportunity to further investigation or discovery.” *Anderson v. Bd. of Sch. Directors of Millcreek Twp. Sch. Dist.*, 574 F. App’x 169, 174 (3d Cir. 2014) (quoting Fed. R. Civ. P. 11(b)). Allegations that are more than conclusory are “entitled to the assumption of truth.” *Connelly v. Lane Const. Corp.*, 809 F.3d 780, 787 (3d Cir. 2016).

6. The court recognizes that the proposed second amended complaint is not written with all the who, what, when, and where's of the communications identified therein. However, given the above standard for reviewing the sufficiency of a complaint, and given that Hikma would be the actual source of the requisite factual information, the court concludes that the proposed second amended complaint contains sufficiently detailed allegations (1) to plausibly give rise to a claim for inducement of patent infringement, and (2) to give Hikma fair notice of such claim. As a consequence, amendment is not futile. Because the instant litigation has not progressed past initial skirmishes,³ there is no undue prejudice to Hikma.

7. **Conclusion.** For the reasons stated, Takeda's motion filed pursuant to Rules 59(e) and 15(a) of the Federal Rules of Civil Procedure (D.I. 124) is granted. The court is aware that the instant litigation will likely have market consequences, and that the court's decision to allow resurrection of the litigation rests upon the veracity of Takeda's allegations. Therefore, under the rather convoluted procedural posture of this case, the court will consider staged discovery, with an initial focus on the evidentiary support for the allegations contained in the second amended complaint, with follow-up discovery by both parties to vet the issue of inducement.



United States District Judge

³Indeed, Hikma has not yet filed an answer. Given the above analysis, one might think that it is time to move past the pleading stage and on to the merits of the litigation.